

These minutes have not been reviewed or approved by the Board of Pharmacy.

**NEBRASKA BOARD OF PHARMACY**  
**MEETING MINUTES**  
**January 27, 2014**

**ROLL CALL**

Ken Saunders, R.P., Chairperson, called the meeting of the Board of Pharmacy to order at 8:37 a.m. in the Lighthouse Room of the Country Inn & Suites, located at 5353 North 27<sup>th</sup> Street, Lincoln, Nebraska. The agenda was provided to Board members, posted on a public bulletin board in the Nebraska State Office Building, posted on the Department's website, and e-mailed to the "interested parties" list prior to the meeting. The following Board members answered roll call:

Kenneth Saunders, R.P., Chair  
Michael Losee, Vice-Chair  
Robert Marshall, R.P., Secretary  
Jennifer King, R.P.  
Patricia Gollner, R.P.

A quorum was present and the meeting convened.

Also present were: Lisa Anderson, Assistant Attorney General; Julie Agena, Assistant Attorney General; Mike Rueb, R.P., Pharmacy Inspector; Gary Cheloha, R.P., Pharmacy Inspector; Dean Willson, Jr., R.P., Pharmacy Inspector; Duane Newland, Investigator; Roger Brink, Department Legal; Suzanna Glover-Ettrich, Department Legal; Becky Wisell, Program Manager and Vonda Apking, Health Licensing Coordinator.

Saunders announced that there is a copy of all the public documents being reviewed at this meeting available in the meeting room pursuant to the Open Meetings Act.

**REVIEW OF AGENDA**

**Adoption of Agenda**

Marshall moved, seconded by Losee, to approve the agenda as presented with the Chair having the authority to rearrange as needed. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: none. Absent: none. Motion carried.

**Additions, Modification, Reordering**

The Board requested that the following applications be removed from the consent agenda:

Kelsey Christensen – Pharmacy Technician application  
Jason Hartman – Pharmacy Technician application  
Shelby Roach – Pharmacy Technician application  
David Rohrer – Pharmacy Technician application  
Nicholas Roth – Pharmacy Technician application  
Rachael Tullis – Pharmacy Technician application  
Theresa Turner – Pharmacy Technician application

**Adoption of Consent Agenda**

Gollner moved, seconded by King, to approve the consent agenda as amended. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: none. Absent: none. Motion carried.

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### **DESIGNATION OF THE METHOD BY WHICH THIS BODY WILL GIVE PUBLIC NOTICE OF ITS MEETINGS**

Wisell explained that the Board voted at its September 2013 meeting to post meeting agendas at the Nebraska State Office Building, to e-mail agendas to the interested parties list, and to post agendas on the Department's website. Gollner moved, seconded by Marshall, that public meeting notices for the Board of Pharmacy will be posted at the Department, posted on the Department's website, and e-mailed to the "interested parties" list. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

### **UPDATE INFORMATION ON TRAVEL REIMBURSEMENT BY THE DEPARTMENT**

Wisell explained that the Department's reimbursement policy, based on statutory language, requires that Board members are required to submit their request for travel expense reimbursement form and supporting documents within 60 days from the date they returned from their travel. Department accounting cannot reimburse expenses on reimbursement requests received later than the 60 days.

### **INVESTIGATIONAL REPORTS, DISCIPLINARY REPORTS, CONTROLLED SUBSTANCES AUDIT REPORTS & APPLICATION REVIEW – CLOSED SESSION**

Marshall moved, seconded by Gollner, to close the session at 8:45 a.m. to review investigational reports, disciplinary reports, controlled substances audit reports and applications. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: none. Motion carried.

Marshall moved, seconded by Losee, to open the session at 9:52 a.m. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: none. Motion carried.

### **APPROVAL OF MINUTES**

November 18, 2013

Page 1: No changes.

Page 2: No changes.

Page 3: No changes.

Page 4: Under Questions from the Department's Facilities Licensing Area Regarding Compounding and Labeling, third paragraph, line two, insert a semi-colon after the word pharmacy.

Page 4: Under Report on the Interactive Executive Officer Forum, line two, change "Prescription monitoring" to "Prescription Drug Monitoring Program".

Marshall moved, seconded by Losee, to approve the November 18, 2013, minutes as corrected. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

### **BOARD RECOMMENDATIONS ON APPLICATIONS FOR LICENSURE AND REGISTRATION**

#### **Pharmacy Technician Applications**

Marshall moved, seconded by Losee, to table the pharmacy technician registration application of Jason Hartman for additional information. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Marshall moved, seconded by King, to recommend issuing a pharmacy technician registration to Shelby Roach. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Gollner moved, seconded by Losee, to recommend issuing a pharmacy technician registration to Kelsey Christensen. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Gollner moved, seconded by King, to recommend issuing a pharmacy technician registration to David Rohrer. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Losee moved, seconded by Marshall, to recommend issuing a pharmacy technician registration to Nicholas Roth. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

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Gollner moved, seconded by Losee, to recommend issuing a pharmacy technician registration to Rachael Tullis. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Marshall moved, seconded by King, to recommend issuing a pharmacy technician registration to Theresa Turner. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Pharmacist License Application - CONSENT

**APPROVAL OF PHARMACY TECHNICIAN MANUAL – CONSENT**

**REVIEW OF PHARMACEUTICAL CARE AGREEMENTS – CONSENT**

**FEDERAL DRUG QUALITY AND SECURITY ACT – GARY CHELOHA, RP**

Cheloha presented to information regarding the Federal Drug Quality and Security Act. There were several questions that the Board of Pharmacy should address such as licensing outsourcing facilities; pharmacies compounding drugs for “office use only”; should USP 797 be in Nebraska statutes; should Nebraska enter into “memorandums of understanding” with the Food and Drug Administration (FDA); for outsourcing facilities located outside Nebraska should one or all pharmacists be licensed in Nebraska; should Nebraska statutes and/or regulations address labeling requirements for outsourcing facilities; if outsourcing facilities are not licensed in Nebraska, are they able to receive prescriptions under the current law; should outsourcing facilities be treated similar to central-fill pharmacies; and will Nebraska inspectors inspect outsourcing facilities if they are not licensed. Board discussed whether certain types of facilities could be required to hold both a wholesale drug distributor license and a mail service pharmacy license. Nebraska statutes do not define “office use compounding”. It is the opinion of the Nebraska Board of Pharmacy that a pharmacy can sell a compounded product to a practitioner for “in office use”. Marshall mentioned that the FDA does not define “reconstitution”; however the United States Pharmacopeia (USP) does define “reconstitution” as compounding. Marshall will research other states regarding “reconstitution”. The Inspectors will be attending a training course in Colorado regarding inspecting sterile compounding facilities. Kevin Borchert, RP, mentioned that LB 1017 addresses some issues regarding compounding.

**2014 LEGISLATION**

LB 811 – Provisions and penalties relating to the UCSA

This legislation updates certain types of drugs to coincide with federal law and the level of penalties associated with violating the Uniform Controlled Substances Act. The Board had no comment on this legislation.

Losee stepped out of the meeting at 11:06 a.m.

LB 858 – Pharmacists and health care services in health insurance

This legislation will add additional reimbursement for other pharmacy services. Marshall moved, seconded by King, to send a letter of support for LB 858. Voting aye: Gollner, King, Marshall, and Saunders. Voting nay: None. Absent: Losee. Motion carried.

LB 869 – Change and transfer provisions on prescriptions and controlled substances

This legislation makes Nebraska law consistent with federal law regarding e-prescribing. The legislative hearing was held on January 24<sup>th</sup>.

Losee returned to the meeting at 11:13 a.m.

Gollner moved, seconded by King, to send a letter of support for LB 869. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

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#### LB 1001 – Legalize industrial hemp and exempt it from the UCSA

The legislation would legalize the use of hemp for industrial use such as rope and clothing. Kevin Borchert, RP, commented that the Nebraska Pharmacists Association has chosen to watch this legislation and it is the NPAs understanding that the intent of this bill is not for human consumption. The Board had no comment on this legislation.

#### LB 1017 – NPA Rewrite of Pharmacy Practice Act

This legislation updates the Pharmacy Practice Act including but not limited to updating the definition of compounding, automated dispensing, putting the regulation of hospital pharmacies back under the Board of Pharmacy, adding Medication Therapy Management and other pharmaceutical services to the practice of pharmacy definition, and eliminating the pharmacy technician manual. Wisell mentioned that the legislation mentions dispensing practitioner but dispensing practitioner is not defined and requested that a definition of dispensing practitioner be added to the legislation by an amendment. Wisell also questioned why physician assistants were stricken from 38-2850(1) exemption. Mr. Borchert explained that because physician assistants do not have independent practice authority. Wisell mentioned that if physician assistants are stricken from 38-2850(1) then they need to be added to 38-2850(5). Gollner moved, seconded by King, to send a letter of support for LB 1017. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

#### LB 1072 – Prescription Monitoring and Health Information Exchange Act

This legislation creates a prescription drug monitoring program similar to surrounding states. Joni Cover, NPA, mentioned that the NPA would recommend support if certain amendments were made. Wisell mentioned that this is similar to LB 535 which is a carry-over bill. Ms. Cover mentioned that LB 535 could be combined with LB 1072 or totally removed. Marshall questioned whether the Board of Medicine supported this legislation. Wisell explained that the Board of Medicine and Surgery supported this legislation and re-affirmed their support of LB 535. Wisell explained that the Board of Medicine and Surgery are in favor of a more traditional prescription drug monitoring program. The legislation does remove the patient's ability to opt out of the program. Anderson mentioned that there should be a provision to allow the Department's Investigations Division to receive information from the program. Ms. Cover mentioned that the NPA was against making the funding of the program coming only from pharmacy. Marshall moved, seconded by Saunders, to send a letter of support for LB 1072 addressing allowing the release of information to the Department's Investigations Division and proper funding. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

#### LB 1078 – Nebraska Telehealth Act, establishment of a patient relationship through video conferencing, and require insurance coverage for telehealth services

Wisell questioned whether there was an implication that pharmacists would have to establish a patient relationship that currently pharmacist are not required to do. The Board did not have the same concern with the language. Marshall moved, seconded by King, to send a letter of support for LB 1078. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

#### LB 1102 – Redefine marijuana and authorize the medical use of hemp extract

This legislation would allow hemp oil to be used medically for certain diseases in children. Marshall mentioned that the legislation doesn't address how it is going to be dispensed or regulated. The Board did not comment on this legislation.

Other legislation was mentioned such as LB 752 which changes certain assault provisions such as assaulting a healthcare professional. Gollner moved, seconded by King, to send a letter of support for LB 752 with a request to amend so it includes pharmacy. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

The Board thanked Ms. Cover for all the work that was put into LB 1017.

#### **HY-VEE CENTRAL FILL PHARMACY MODEL – KRISTIN WILLIAMS, RP**

Kristin Williams, RP, Hy-Vee, addressed the Board regarding Hy-Vee's Central Fill Pharmacy located in Des Moines, Iowa. Ms. Williams explained the process that occurs at the central fill pharmacy and that

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pharmacists at the Nebraska pharmacy can see what drugs are coming back from the central fill pharmacy which are mostly maintenance medications. Wisell explained the Board determined at their last meeting that either all the pharmacists at the central fill location need to be licensed in Nebraska or the pharmacist at the Nebraska pharmacy need to visually inspect the prescriptions as they are returned to the pharmacy. Ms. Williams asked why all the pharmacists, at the central fill pharmacy, have to be licensed in Nebraska instead of just one pharmacist similar to a mail service pharmacy? Roger Brink, Department Legal, explained that a consumer has chosen to have a pharmacy-patient relationship with the mail service pharmacy but not necessarily does the consumer know that Hy-Vee chooses to fill certain prescriptions using a central fill pharmacy.

### **PRACTICE QUESTIONS**

Can a medical student repackage, label, and dispense prescription drugs that are not prescription drug samples under a Dispensing Practitioner Pharmacy License?

It is the Board's opinion that a medical student could repackage, label, and dispense prescription drugs if they were registered as a pharmacy technician and supervised by a pharmacist.

Does the Nebraska Board of Pharmacy allow a compounded schedule II controlled substance preparation to be resold by a practitioner that has purchased the product from a pharmacy?

It is the Board's opinion that a pharmacy could compound a schedule II controlled substance to be resold by a practitioner but the pharmacy would need to make sure that they don't need a wholesale drug distributor license and the pharmacy would need to make sure they adhere to section 503A of the Food Drug and Cosmetic Act.

Questions from the Department's Facilities Licensing Area Regarding Compounding and Labeling (carried over from 11-18-13 meeting)

May someone other than a pharmacist or pharmacy tech affix a label to a bulk product (i.e. an inhaler) or to an already dispensed medication that has had a dosage change? If so, what is the pharmacist's responsibility to follow up on the correct labeling (i.e. re-dispense the medication, re-label the medication, review the label and initial, etc.)? These medications would have the potential to be sent home with the client upon discharge from the facility or service.

For hospitals: Hospitals are exempt from the Practice of Pharmacy.

For other healthcare facility and service types: It is the Board's opinion that other healthcare facilities should check the medication administration record known as the "MAR" or the pharmacy should affix a new label. The new label can only be affixed by a pharmacist, pharmacist intern or a pharmacy technician.

Additional questions that came up in subsequent discussions:

When one medication in a multi-drug package through automated dispensing is discontinued, does the whole package need to go back to the pharmacy or can the nurse remove the discontinued medication? This happens often with dose changes, hold parameters, and patient refusals.

It is the Board's opinion that these medications should be quarantined off to the side.

If an emergency box contains a drug that needs reconstitution, can the reconstitution be done in a long-term care facility by someone other than a pharmacist or pharmacy technician?

It is the Board's opinion is that yes, someone other than a pharmacist or pharmacy technician can reconstitute for immediate use.

Are pharmacy technicians allowed to compound?

It is the Board's opinion that yes, a pharmacy technician is allowed to compound under the immediate personal guidance and direction of a pharmacist. Supervision and verification are defined in the Nebraska Practice of Pharmacy Act.

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Is it acceptable to reprint a prescription from an electronic health record system due to printing malfunction, provided there is an audit trail, or must the reprinting capabilities be removed?

It is the Board's opinion that the prescribing practitioner should cancel the prescription and re-issue a new prescription.

### **NATIONAL ASSOCIATION OF BOARDS OF PHARMACY (NABP) ISSUES**

#### **Report on the Compliance Officer Forum**

Willson attended this meeting. Topics of discussion were:

- Sister State Disciplinary action and the Importance of Information Sharing Among States;
- How to Effectively Build a Disciplinary Case;
- What Causes Variability in Inspections;
- Where is Track and Trace in Regards to Prescription Drug Pedigrees;
- Differentiating Between USP 795 and 797;
- NABP Prescription Monitoring Program Interconnect Update; and
- NABP's Verified Pharmacy Program

There were other topics presented but not discussed which included medical marijuana dispensing, pill mill type pain clinics/internet pharmacies, problems with prescription drug monitoring programs, illegal compounding, validation problems with controlled substance prescriptions, and virtual wholesalers. Willson thanked the Board and the Department for allowing him to attend this meeting.

#### **District-V Meeting – August 2014**

Saunders, Marshall, King and Losee expressed interest in attending District V meeting in South Dakota. Saunders, King, Losee and Gollner expressed interest in attending NABPs Annual Meeting in Arizona in May 2014. Staff will submit travel authorization requests.

### **ELECTION OF OFFICERS**

Saunders moved, seconded by King, to nominate Marshall for Chair. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Marshall moved, seconded by Saunders, to nominate King as Vice-Chair. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

Marshall moved, seconded by Losee, to nominate Gollner as Secretary. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: None. Motion carried.

### **GENERAL INFORMATION**

Nothing to discuss at this time.

### **ADJOURNMENT**

Losee moved, seconded by Gollner, to adjourn the meeting at 2:07 pm. Voting aye: Gollner, King, Losee, Marshall, and Saunders. Voting nay: none. Motion carried.

Respectfully submitted,

Robert Marshall, R.P., Secretary  
Board of Pharmacy